

NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DAIICHI PHARMACEUTICAL CO., LTD. and
DAIICHI PHARMACEUTICAL CORPORATION,

Plaintiffs,

v.

APOTEX, INC. and APOTEX CORP.,

Defendants.

Civ. No. 03-937 (WGB)

MEMORANDUM OPINION

APPEARANCES:

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BASSLER, SENIOR DISTRICT JUDGE:

Plaintiffs Daiichi Pharmaceutical Co. Ltd., and Daiichi Pharmaceutical Corporation (collectively as "Daiichi" or "Plaintiffs") filed a motion *in limine* to preclude defendants Apotex, Inc. and Apotex Corp. (collectively as "Apotex" or "Defendants") from asserting an affirmative defense of failing to name the proper inventors of Daiichi's patent pursuant to 35 U.S.C. § 102(f).

For the reasons set forth below, Daiichi's motion is **granted**.

I. BACKGROUND

Daiichi brought suit against Apotex alleging patent infringement of all seven claims of Daiichi's U.S. Patent No. 5,401,741 ("the '741 patent"), entitled a "Topical Preparation for Treating Otopathy." Daiichi now argues that Apotex did not sufficiently put Daiichi on notice of the defense that it is not entitled to the '741 patent for failure to name the proper inventors pursuant to 35 U.S.C. § 102(f). Section 102 states: "A person shall be entitled to a patent unless... (f) he did not himself invent the subject matter sought to be patented...."

Daiichi argues that section 102 provides an affirmative defense that must be pled in a way that sufficiently gives a plaintiff notice of the defense, and by failing to do so Apotex waived such defense. Furthermore, Daiichi contends that allowing

Apotex to present evidence to that end not only unduly prejudices Daiichi but also thwarts the purpose of contention interrogatories.

Apotex asserts that it raised the section 102(f) issue in its Amended Answer. Apotex also argues that Fed. R. Civ. P. 8(c) does not list 102(f) as an affirmative defense and, therefore, it need not be specifically pleaded. In addition, Apotex makes argues that Daiichi will not be prejudiced and was aware of the likelihood of the defense because of questioning during depositions. Moreover, Appotex argues Daiichi was in possession of documents that suggested the defense would be raised.¹

II. DISCUSSION

A. Affirmative Defenses Under Rule 8(c)

Rule 8(c) of the Federal Rules of Civil Procedure requires that "In a pleading to a preceding pleading, a party shall set forth affirmatively... any [] matter constituting an avoidance or affirmative defense...." (Emphasis added.) The Rule itself does not list every affirmative defense. The fact that the defense under 35 U.S.C. § 102(f) is not provided for under Rule 8(c) does

¹The Court will not address Apotex's Fed. R. Civ. P. 15(b) argument because it does not apply. "Although Rule 15(b) does allow a court, under certain circumstances, to amend pleadings to conform to evidence even when the opposing party objected to that evidence, application of any portion of Rule 15(b) is appropriate only when an issue 'not raised by the pleadings' has, in fact, been presented." Koch v. Koch Indus., 203 F.3d 1202, 1218 (10th Cir. 2000); see also Deakyne v. Commissioners of Lewes, 415 F.2d 290 (3d Cir. 1969).

not mean that it falls outside the category of affirmative defenses; this is evident from the plain language of Rule 8(c). See e.g. Williams v. Ashland Engineering Co., Inc., 45 F.3d 588, 593 (1st Cir. 1995) (discussing preemption as an affirmative defense); Cornwall v. U.S. Const. Mfg. Inc., 800 F.2d 250, 252 (Fed. Cir. 1986) (discussing invalidity as an affirmative defense); Freedman Seating Co. v. American Seating Co., 420 F.3d 1350, 1363 n.6 (Fed. Cir. 2005) (discussing enforceability as an affirmative defense); Ray v. Kertes, 285 F.3d 287, 291-92 (3d Cir. 2002) (discussing exhaustion as an affirmative defense); Shechter v. Comptroller of City of New York, 79 F.3d 265, 270 (2d Cir. 1996) (discussing immunity as an affirmative defense); Kennan v. Dow Chemical Co., 717 F.Supp. 799, 808-09 (M.D.Fla. 1989) (discussing preemption as an affirmative defense).

The issue for the Court is whether section 102(f) falls within the category of a matter constituting avoidance or an affirmative defense. "Generally speaking, the rule's reference to 'an avoidance or affirmative defense' encompasses two types of defensive allegations: those that admit the allegations of the complaint but suggest some other reason why there is no right to recovery, and those that concern allegations outside of the plaintiff's prima facie case that the defendant therefore cannot raise by a simple denial in the answer." 5 CHARLES A. WRIGHT & ARTHUR R. MILLER, FEDERAL PRACTICE AND PROCEDURE § 1271 (3d ed. 2004).

The argument underlying section 102(f), that a plaintiff is not entitled to recover because he is not the true inventor, falls well within the category of affirmative defenses considered by other courts as well as the first type of defensive allegations listed by Wright and Miller.

B. Pleading Affirmative Defenses

"Parties are generally required to assert affirmative defenses early in litigation, so they may be ruled upon, prejudice may be avoided, and judicial resources may be conserved." Robinson v. Johnson, 313 F.3d 128, 134 (3d. Cir. 2002). The Rule technically requires that such a defense be pleaded in the answer. Id. at 135. The purpose behind Rule 8(c) is to put "plaintiff on notice well in advance of trial that defendant intends to present a defense in the nature of an avoidance." Marino v. Otis Engineering Corp., 839 F.2d 1404, 1408 (10th Cir. 1988) (internal citations omitted). "A defendant should not be permitted to 'lie behind a log' and ambush a plaintiff with an unexpected defense." Perez v. United States, 830 F.2d 54, 57 (5th Cir. 1987) (internal citations omitted).

In order to assert an affirmative defense under Rule 8(c) the pleading party must at least put plaintiff on reasonable notice of that defense. While some courts have considered harmless a technical failure to comply with Rule 8(c), others have taken into account the stage of the proceeding in deciding

whether fair notice was satisfied. See Venters v. City of Delphi, 123 F.3d 956, 968-69 (7th Cir. 1997) (holding that defendants' statute of limitations defense, submitted after an exhaustive discovery process and a trial scheduled a month away, deprived the plaintiff of fair notice and a reasonable opportunity to respond) (cited in Robinson, 313 F.3d at 136).

The Court must therefore determine whether Apotex put Daiichi on reasonable notice of its intent to argue section 102(f). Apotex argues that Daiichi was fully aware that the issue of the proper inventor was on the table: (1) section 102(f) was raised in its Answer, (2) the issue was explored throughout discovery and depositions, and (3) Daiichi's internal documents flagged the issue.

C. Whether Sufficient Notice Was Provided

While Apotex's Answer and Additional Defenses, at paragraph 20, broadly lists 35 U.S.C. § 102 among other statutes as an Additional Defense, this is insufficient to apprise Daiichi that it is raising the inventorship defense. As the Court in Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc. 41 U.S.P.Q.2d 1770, 1773 (N.D.Cal. 1996), noted, "[s]ince [35 U.S.C.] sections 101, 102, 103, and 112 provide numerous grounds for finding a patent invalid, defendant must provide a more specific statement of the basis for this defense in order to give [plaintiff] fair notice of the claims being asserted."

The purpose of raising an affirmative defense early on in litigation is to put the plaintiff on reasonably fair notice of that defense. In light of the contention interrogatories and extensive discovery between the parties, broadly citing the statute does not provide sufficient notice. While the general pleading standards of Rules 8(b) and (e) should be "consulted" when considering an affirmative defense, it cannot be said that Apotex's perfunctory listing provides the reasonably fair notice necessary under Rule 8(c). WRIGHT & MILLER at § 1274; see also Cornwall v. U.S. Const. Mfg. Inc., 800 F.2d 250 (Fed. Cir. 1986); Shechter v. Comptroller of City of New York, 79 F.3d 265, 270 (2d Cir. 1996).

Apotex also claims that Daiichi was on notice of its section 102(f) claims because the issue was explored throughout discovery and depositions. Defendants, however, cite no authority for the contention that a plaintiff may be sufficiently put on notice of an affirmative defense by the implications underlying discovery requests. This diverges from the purpose of providing notice of an affirmative defense and it makes no sense. In essence, Apotex argues Daiichi should be considered on reasonable notice of the section 102(f) claim based on Defendants' trial tactics. If this were true, it would undermine the purpose of early notification of affirmative defenses; a plaintiff would have to guess whether the affirmative defense will be raised, along with any other

defenses, at trial based on the materials sought in discovery or the line of questions asked during depositions.

In Transclean Corp. v. Bridgewood Services, Inc., the court dealt with a similar issue and reached a similar result. Transclean Corp. v. Bridgewood Services, Inc., 77 F.Supp.2d 1045, 1062 (M.D.Minn. 1999) rev'd on other grounds, 290 F.3d 1364 (Fed. Cir. 2002). The defendant argued that plaintiffs were put on notice of its contentions by way of discovery requests. The court held that following this line of thinking would "condone 'hide the ball' discovery practices, and subvert the purposes of Rule 26(e), by permitting contention discovery to be an elusive guessing exercise." Id.

Daiichi was not implicitly put on notice by its discovery requests and its questions during depositions.

The same can be said for Apotex's argument that Daiichi's own documents put Daiichi on notice of the issue of inventorship. The fact that Daiichi is in possession of documents relating to inventorship does not mean it is on notice of an affirmative defense under section 102(f). How would the Plaintiffs know which of its documents or evidence the Defendants plan to introduce to prove the section 102(f) defense? Only Apotex's discovery responses could properly provide Daiichi with notice of their 102(f) claim before the expiration of the discovery period. See Transclean Corp., 77 F.Supp.2d at 1062. The purpose of an

affirmative defense is to hedge against the complete litigation of a full defense. The Court rejects Apotex's arguments that Daiichi was on reasonable notice to the section 102(f) defense based on discovery, depositions, and Daiichi's own documents.

This conclusion is further supported by Apotex's failure to raise the defense of 102(f) in its answers to Daiichi's contention interrogatories. In their third set of interrogatories to Defendants, interrogatory number 32, Plaintiffs make the following request:

Explain the factual and legal bases for any and all allegations by Apotex that any of claims 1-7 of Daiichi's patent-in-suit is invalid or otherwise unenforceable due to alleged patent misuse and identify all knowledgeable individuals and the documents and deposition testimony reviewed, considered and/or relied on in support thereof.

In its response, Apotex provides no specific justifications for its belief that Daiichi is not entitled to the '741 patent based on section 102(f). Rather, Apotex blandly states that it "adopts and incorporates by reference all prior art reference and factual and legal bases... pursuant to 35 U.S.C. § 102...." The Court emphasizes the fact that a section 102(f) claim is not a run-of-the-mill defense. "[M]isjoinder or nonjoinder of inventors must be proven by facts supported by clear and convincing evidence." Trovan, Ltd. v. Sokymat SA, Irori, 299 F.3d 1292, 1301 (Fed. Cir. 2002). Multiple inventors may be involved without equal rights to the patent. Id. at 1302.

Inventorship is determined on a claim-by-claim basis, and involves a complex analysis of the contributions of each individual to the subject matter at issue. Id. This is the type of complicated information that is best considered as early in the litigation as possible so as to clearly define the issues for trial.

The purpose of contention interrogatories is to narrow and define issues for trial beyond what may be ascertained from the parties' pleadings. Transclean Corp., 77 F.Supp.2d at 1062; Thorn EMI N. Am. v. Intel Corp., 936 F.Supp. 1186, 1191 (D.Del. 1996) ("The court will prevent a party from raising a claim or defense at trial that was not adequately described in a response to a contention interrogatory."); Sperling v. Hoffman-La Roche, Inc., 924 F.Supp. 1396, 1411-12 (D.N.J. 1996). "It is well-recognized that complete and accurate responses to discovery are imperative to the functioning of the modern trial process... The 'modern instruments of discovery' are thus a principal means by which trials are rendered 'less a game of blindman's bluff and more a fair contest with the basic issues and facts disclosed to the fullest practicable extent.'" Averbach v. Rival Mfg. Co., 879 F.2d 1196, 1201 (3d. Cir. 1989) citing United States v. Procter & Gamble Co., 356 U.S. 677, 682 (1958). A failure to disclose may be grounds for automatic exclusion of the evidence under Fed. R. Civ. P. 37(c)(1). See Transclean Corp., 77

F.Supp.2d at 1063 (considering four factors in "assessing the substantiality of any proffered justification for the failure to disclose, as well as the harmlessness of that failure.")

Apotex does not dispute the fact that an affirmative defense as to the proper inventor was not fully laid out in its responses to Daiichi's interrogatories, rather it argues that it "assumed that the inventorship issue had been raised by Bausch & Lomb...." Apotex's Opp. Br. at 16 (emphasis added). Such an assumption does not excuse Apotex's failure to sufficiently address the affirmative defense in its answer or responses to interrogatories.

"A party who fails to raise an affirmative defense in a timely fashion is deemed to have waived the defense." McCoy v. Bd. of Trs. of the Laborers' Int'l Union Local #222 Pension Plan, 188 F.Supp.2d 461, 468 (D.N.J. 2002) aff'd, 2003 U.S. App. LEXIS 5756 (3d Cir. 2003); see also WRIGHT & MILLER at § 1278 ("It is a frequently stated proposition of virtually universal acceptance by the federal courts that a failure to plead an affirmative defense as required by Federal Rule 8(c) results in the waiver of that defense and its exclusion from the case..."). The Third Circuit has held that a defendant does not waive an affirmative defense if he raised the issue at a pragmatically sufficient time, and the plaintiff was not prejudiced in its ability to respond. Eddy v. V.I. Water & Power Auth., 256 F.3d 204, 209

(3d. Cir. 2001). The Court, however, finds that the issue of proper inventorship was not raised at "a pragmatically sufficient time" and Daiichi will be prejudiced by Apotex's eleventh-hour defense.

Daiichi served three separate interrogatories on Apotex. Apotex did not respond with a clear statement on the grounds for its section 102(f) defense. Only after the close of extensive discovery and at the hearing to set the trial date did Apotex place Plaintiffs on notice. See 07-21-2005 Transcript of Hearing Before Magistrate Judge Arlea at 50-51. The Court, therefore, finds this affirmative defense has been untimely raised and is deemed waived.

Daiichi is now without opportunity to take discovery on the section 102(f) defense or retain an expert on the issue. The issue of true inventorship is complex and is determined on a case-by-case basis. Travan, 299 F.3d at 1302. It involves comparing the contributions of each asserted co-inventor to each claim of the patent. Id. The contributors must prove their contribution with corroborating evidence; that is, more than their own testimony. Id. Because of the intricacy of a 102(f) claim it demands adequate notice so that a plaintiff might properly counter the argument.

The Court agrees with Daiichi's argument that Apotex has frustrated the purpose of contention interrogatories.

Affirmative defenses need to be asserted early in litigation to avoid this type of surprise and undue prejudice. See Long v. Wilson, 393 F.3d 390, 397 (3d Cir. 2004). If there is good cause for not raising an affirmative defense in the answer, "it must be raised as early as practicable thereafter." Id. at 398 (internal citations omitted). The Court finds that Apotex missed several opportunities throughout discovery to raise the section 102(f) defense, to fully flesh out the basis behind the claim, and to give Daiichi ample notice and time to demonstrate why the affirmative defense should not succeed. The Court, therefore, holds Apotex has waived its section 102(f) affirmative defense.

III. CONCLUSION

For the foregoing reasons, Daiichi's motion *in limine* is **granted**. Apotex is precluded from asserting an affirmative defense of alleged improper inventorship pursuant to 35 U.S.C. § 102(f).

An appropriate Order follows.

/s/ William G. Bassler
William G. Bassler, U.S.S.D.J.

Dated: November 1, 2005